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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,230	02/04/2004	Jan Johansson	290168.121 US4	2415

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EXAMINER	
WOODWARD, CHERIE MICHELLE	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
06/15/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/772,230	JOHANSSON, JAN	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 5-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response and Amendments to the claims, drawings, and specification, filed 2 April 2007, are acknowledged and entered. Claims 5-9 are pending and under examination.

Specification

2. The objection to the specification regarding the cross-references to related applications, is withdrawn in light of Applicant's amendments to the specification.

3. The objection to the specification because of alterations on page 6, is withdrawn in light of Applicant's amendments to the specification.

Drawings

4. The objection to the drawings because Figures 10 and 11 contain multiple figures, is withdrawn in light of Applicant's amendments to the drawings.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 5-9 under 35 U.S.C. 102(b) as being anticipated by Soto et al., (Biochem and Biophys Res Com. 1996; 226:672-680, is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the key to the claimed invention is the recognition of discordant helix and stabilization of an α-helical form of a discordant helix. Applicant argues that Soto et al., do not teach discordant helices and does not suggest stabilizing an α-helical form of a discordant helix, but is rather directed to binding peptides to a β-sheet form of an Aβ peptide. Applicant argues that Soto et al., does not disclose any method for identifying a protein susceptible to forming amyloid or identifying such proteins by identifying discordant helices. Applicant restates the definition of "discordant helix" set forth

in the specification as "an amino acid sequence that is predicted to be able to form an α-helix and is also predicted to be able to form a β-strand." Applicant argues that although Soto et al., does disclose the presence of hydrophobic residues in an Aβ peptide, other proteins are known in the art that have hydrophobic regions, but which are not proteins that form amyloids. Applicant also argues that Soto et al., suggests treating a subject with a compound that stabilizes an α-helical form of a discordant helix-containing polypeptide that forms amyloid, or where the amyloidosis is selected from the group consisting of prion diseases and Alzeheimer's disease. Applicant's arguments have been fully considered, but they are not persuasive.

Soto et al., teach the use of the Chou-Fasman structure prediction algorithm to determine the probability that residues 15-25 of Aβ will form a β-sheet (p. 673, paragraphs 4 and 5; p. 674, Figure 1) (see also, for exemplary purposes only, Chou et al., (Ann Rev Biochem. 1978; 47:251-76, especially at 257; and Chou et al., Biophys J. 1979 June; 26:367-383)). It is well known in the art that residues 15-25 of the Aβ protein represent residues that can form either α-helices or β-sheets (see, for exemplary purposes only, Mihara et al., Biopolymers (Peptide Science). 1998; 47:83-92, especially at p. 85, Figure 2). Thus, the residues taught by Soto et al., meets Applicant's definition of a "discordant helix" as defined in the instant disclosure (p. 4), as an amino acid sequence that is predicted to be able to form either an α-helix or β-sheet.

The specification does not limit the manner in which a "discordant helix" may be identified. Page 4 of the specification recites that "[a] discordant helix can be identified [by] using structure analysis programs that predict [the] secondary structure of polypeptides" (lines 8-9). Further, "[a] sequence that is predicted to form [an] α-helix and β-strand [sheet] is a discordant helix" (lines 11-12). "A discordant helix can also be naturally occurring in a wild type or mutant polypeptide" (lines 13-14). The specification also fails to specifically limit the length of the discordant helix sequences. Instead, it limits only by way of example, "[s]uch sequences can be longer, e.g. 7, 8, 9, 10, 11, 14, 16, 18, 22, 24, or 26 amino acids in length" (page 4, lines 16-17).

Soto et al., teach that pH, peptide concentration, and solvents can influence the conformation of Aβ peptides and that these factors can determine whether the Aβ peptide adopts an α-helix or a β-sheet conformation (p. 675, first paragraph). Soto et al., also teach that hydrophobicity facilitates monomeric interactions that thermodynamically drive Aβ peptides to convert from α-helices to β-sheets, which produce amyloid fibrils (p. 673, first paragraph). Applicant's claims broadly encompass Aβ peptides, among others.

Soto et al., also teach the use of an inhibitor of Aβ fibrillogenesis peptide 1 (iAβ1), an 11 amino acid peptide composition that prevents the adoption of β-sheets in Aβ so that the maintenance of α-helices is favored (p. 674, second paragraph). Quantitative evaluation of the effect of iAβ1 on *in vitro* Aβ fibrollogenesis showed that iAβ1 composition inhibited the transition to β-sheets in Aβ, compared to assays in which the inhibitor iAβ1 was not present (p. 675, last paragraph; see also, Figure 3, p. 676, and Figure 4, page 677).

Soto et al., teach that the anti-β-sheet peptides and derivatives, including cyclic peptides or peptide mimetic molecules may be used to prevent and/or retard amyloidosis in vivo in Alzheimer's disease and other types of amyloid related disorders (p. 678, last paragraph to p. 679, first paragraph).

Conclusion

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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